REMARKS

Claim 6 has been canceled, and claims 2 and 3 have been amended to more definitely set forth the invention and obviate the rejections. In addition, new Claims 7-16 have been added. Support for the amendment of claims 2 and 3 can be found in the Specification on page 12, lines 6-14. Support for new Claims 7-16 can be found in the Specification from page 10, line 7, to page 12, line 17. The present amendment is deemed not to introduce new matter. Claims 2-5, and 7-17 are in the application.

Reconsideration is respectfully requested of the rejection of Claims 2-6 under 35 U.S.C. § 103(a) as being unpatentable over Castaneda in view of Clynch (USPN 6,463,351) and Tower (USPN 5,161,547).

The claims herein call for a master to be formed in accordance with shape information obtained concerning the inner shape of a tubular living-body tissue of a person to be treated. Thereafter, the outer surface of the master is wrapped with wires having a shape memorization property.

It is respectfully submitted that, as the Examiner has admitted on page 2 of the instant Office Action, the Castaneda reference nowhere discloses the steps of obtaining inner shape information regarding a tubular living-body tissue of a patient

to be treated using mechanical methods, and then using that information to form a three dimensional master having an inner surface or outer surface substantially similar to the inner shape of the tubular living-body tissue, followed by the step of wrapping the outer surface of the master with wire having shape memorization property. On the contrary, that teaching or suggestion comes only from the present application, and constitutes an important element or aspect of the present invention.

To cure said deficiencies, the Examiner has cited two additional secondary references, i.e., the Clynch and Tower references. The newly cited secondary Clynch reference discloses a method for producing prosthetics or orthotic devices, by first making a model of the body part using conformable fabric impregnated with a settable resin (i.e., making a conventional "cast"). This model is then scanned to produce a digitized model of the OUTER surface of a portion of the human body. Thus, Clynch requires that a cast first be made manually of the EXTERNAL body part, a digital image formed from said case, and then an ORTHOTIC or PROSTHETIC be formed based on the digital image. Obviously, Such a procedure CANNOT be used to create a master of a hollow human tissue, such as a blood vessel.

The secondary Tower reference discloses a method of forming an intravascular radially expandable stent. However, the mandrel of Tower is not equivalent to the master claimed herein, as the mandrel is not formed based on a 3-dimensional image of the hollow human body tissue as herein. Rather, the mandrel of tower is simply a generic form for the stent disclosed therein. The stent of Tower must then be mounted on a balloon catheter, and inserted into the appropriate blood vessel (see column 4, lines 29-30). "Once the stent is properly located and verified by fluoroscopic or other means, the balloon catheter is inflated to radially expand the serpentine wire sleeve 18" (see column 3, lines 28-36).

From the above disclosure of Tower, it can be easily seen that there is no shape-memorization process involved in the method of Tower. Rather, the stent is manually expanded inside of the body, so as to attempt to permanently approximate the internal dimensions of the target tissues by actual bending of the wires. It is respectfully submitted that such a method cannot obtain the preciseness of the method claimed herein, and involves much greater difficulty in installation of the stent into the patient.

In contrast, the present invention as now claimed herein calls for a stent **matching an inner shape of a tubular living-body tissue**

of a patient, formed by the steps of:

(a) obtaining inner shape-information regarding a tubular living-body tissue of a patient to be treated,

(b) using the inner shape information to form a three dimensional master, having an inner surface or outer surface with a shape substantially similar to the inner shape of the tubular living-body tissue of the patient to be treated,

(c) wrapping the outer surface of the master with wire having a shape memorization property,

(d) memorizing the shape of said master to said wire wrapped around the outer surface of the master by heating, and

(e) treating the wire to affect shape-memorization thereof.

Further, a method of manufacturing the stent matching an inner shape of a tubular living-body tissue of a patient to be treated, is provided comprising the steps of:

obtaining inner shape information regarding the tubular living-body tissue of the patent to be treated by using a mechanical method;

forming a master in accordance with the shape information so that the master has a three dimensional inner surface or outer surface substantially similar to the inner shape of the tubular living-body tissue; and

wrapping the outer surface of the master with wires having

shape-memorization property to weave the stent; **and**

performing shape memorization upon the wire by heating said wire wrapped around said master.

It is believed that the combination of 3 cited references fails to teach or suggest modifying the process of Castaneda by using the data from a three dimensional image (as claimed herein) to generate a model of the interior of a hollow human tissue (as claimed herein, which differs significantly from forming an orthotic or prosthetic as taught by Clynch), and THEN using this model to generate a master (as opposed to simply using a generic mandrel as disclosed by Tower), followed by wrapping of the wire around the master and heating of the wire wrapped around the master to memorize the shape thereof (as now claimed herein in amended claims 2 and 3).

Citing references which merely indicate that isolated elements and/or features cited in the claims are known is not a sufficient basis for concluding that the combination of claimed elements would have been obvious, *Ex parte Hiyamizu* 10 PQ2d 1393 (BPAI 1988), absent evidence of a motivating force which would impel persons skilled in the art to do what applicant has done. The mere fact that references can be combined does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Fritch* 972 F2d 1260,

23 PQ2d 178 (CAFC 1992).

It is respectfully submitted that there, in fact, is no suggestion in either of the 3 cited prior art references of combining the teachings of same to arrive at the now claimed invention. In particular, it is believed that there is no teaching or suggestion in the combination of cited references of obtaining 3 dimensional inner shape-information of a tubular living-body tissue of a patient to be treated, using the inner shape information to form a three dimensional master, having an inner surface or outer surface with a shape substantially similar to the inner shape of the tubular living-body tissue of the patient to be treated, wrapping the outer surface of the master with wire having shape memorization properties, memorizing the shape of said master to said wire wrapped by heating the wire, and treating the wire to affect shape-memorization thereof. Rather, this teaching comes only from the present invention, and constitutes an important element or aspect thereof.

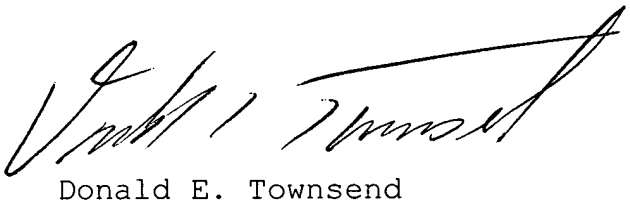
In view of the above cited legal authorities, as well as the amendments to the claims made herein, it is respectfully submitted that the now cited combination of references fails to render unpatentably obvious the subject matter now called for herein. Consequently, the Examiner would be justified in no longer maintaining the rejection. Withdrawal of the rejection is

accordingly respectfully requested.

In view of the foregoing, it is respectfully submitted that the application is now in condition for allowance, and early action and allowance thereof is accordingly respectfully requested. In the event there is any reason why the application cannot be allowed at the present time, it is respectfully requested that the Examiner contact the undersigned at the number listed below to resolve any problems.

Respectfully submitted,

TOWNSEND & BANTA



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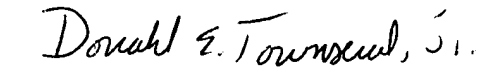

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Date: February 27, 2004